

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference P 31,595 PCT	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2006/017999	International filing date ( <i>day/month/year</i> ) 09 May 2006 (09.05.2006)	Priority date ( <i>day/month/year</i> ) 10 May 2005 (10.05.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ELAN PHARMA INTERNATIONAL LIMITED		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 14 November 2007 (14.11.2007)  Authorized officer <p style="text-align: center; font-weight: bold;">Philippe Becamel</p> e-mail: pt12.pct@wipo.int
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# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
GENE YAO  
SUITE 2600  
1101 MARKET STREET  
PHILADELPHIA, PA 19107

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>P 31,595 PCT</b>		Date of mailing (day/month/year) <b>31 AUG 2006</b>
International application No. <b>PCT/US06/17999</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International filing date (day/month/year) <b>09 May 2006 (09.05.2006)</b>	Priority date (day/month/year) <b>02 November 1998 (02.11.1998)</b>	
International Patent Classification (IPC) or both national classification and IPC <b>IPC: A61K 9/64( 2006.01)</b> <b>USPC: 424/456</b>		
Applicant <b>DEVANE, ET AL</b>		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion <b>27 July 2006 (27.07.2006)</b>	Authorized officer <b>Hasan S. Ahmed</b> Telephone No. 571-272-0700
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US06/17999

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper  
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in electronic form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US06/17999

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-51</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-51</u>	NO
Industrial applicability (IA)	Claims <u>1-51</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-51 lack an inventive step under PCT Article 33(3) as being obvious over Shigeyuki, et. al. Shigeyuki, et. al. teach sustained release microcapsules (note paragraph 0008), including nanoparticles (note paragraph 0040), containing active agent. The nanoparticles may contain vitamin K2 (note paragraph 0085) and calcitonin (note paragraph 0048). The formulation may be in capsule or tablet form (note paragraph 0155) and may contain excipients such as surface stabilizers (e.g. gelatin - note paragraph 0117) and enhancers (note paragraph 0156). The formulation may be prepared by, *inter alia*, homogenization (note paragraph 0123). The formulation may be used to promote osteogenesis (note paragraph 0085). Shigeyuki, et. al. do not teach the specific particle sizes and weight percentages claimed, however these may be determined by routine experimentation. In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a nanoparticulate vitamin K2 composition for the treatment of osteoporosis, as taught by Shigeyuki, et. al.

Claims 1-51 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.